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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,299	08/19/2003	Philip J. Haarstad	P-10855.00	4204
27581	7590	09/07/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924				LUSTUSKY, SARA
ART UNIT		PAPER NUMBER		
		3735		

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/643,299	HAARSTAD ET AL.
	Examiner Sara Lustusky	Art Unit 3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-47 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 16 December 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/16/04 7/20/05</u> . | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
6) <input type="checkbox"/> Other: _____ . |
|---|--|

DETAILED ACTION

Information Disclosure Statement

- The information disclosure statement filed on 1/16/04 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered if a copy of the corresponding reference was not provided.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: (230) as seen in Figure 11. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective

action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: On page 1, in line 2, "priority from" should read - - benefit of - - and in line 4 "from" should read - - of - -.

Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claims 1- 47 are objected to because of the following informalities: For consistency - - suction - - should be inserted before every recitation of "head".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 8, 10 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Snow (Patent 6936001 B1).

Regarding claims 1, 8, 10 and 11, Snow teaches a heart positioning device and method of using the device comprising a flexible suction head (4) (as seen in Figure 2) for conforming to the surface of the heart (as seen in Figure 15), wherein the suction head has a vacuum passageway (82, 84) (as described in lines 46-54 of column 3) (as seen in Figures 5 and 7); a shaft (66) coupled at a distal end to the suction head (64), the shaft having a vacuum lumen (86) (as seen in Figures 2, 4 and 8); a handle (68) coupled to a proximal end of the shaft (66) (as seen in Figure 8) for remote manipulation of the position of the suction head both to and from an axially aligned position using a system of joints (62) providing for a wide range of positions including a 90 degree angle (as described in lines 37-45 of column 3); a means for locking the position of the suction head in a desired position (as described in lines 11-16 of column 4); and a means for remotely changing the position of the head (as described in lines 1-7 of column 3) (as seen in Figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (Patent 6936001 B1) in view of Spence et al. (Patent 6019722).

Snow teaches the heart positioning device of claim 1, as described above, comprising a suction head having a vacuum passageway, a shaft having a vacuum lumen, a handle and a means for remotely changing the position of the suction head. However, Snow does not teach a suction head that has at least three resilient legs.

Spence et al. teaches a heart positioning device comprising a suction head having at least three resilient legs in fluid communication with a vacuum passageway and a handle for manipulation of the position of the suction head (as described in lines 60-67 of column 9, lines 62-67 of column 10, and lines 1-3 of column 11) (as seen in Figures 3 and 4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a suction head comprising at least three resilient legs similar to that taught by Spence et al. with a heart positioning device similar to that taught by Snow as a design choice because the suction head of Spence et al. is capable of performing the same functions as the suction head taught by Snow (as described in lines 31-37 of column 6 of Spence et al.). Furthermore the resilient legs of the suction head taught by Spence et al. provide a more evenly balanced support on the heart thereby reducing the stress at any one point (as described in lines 51-57 of column 6 of Spence et al.).

Claims 3-7, 12, 14-19 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (Patent 6936001 B1) in view of Daniel et al. (Patent 6174307 B1).

Snow teaches the device of claim 1, as described above, comprising a flexible suction head (4) (as seen in Figure 2) for conforming to the surface of the heart (as seen in Figure 15), wherein the suction head has a vacuum passageway (82, 84) (as described in lines 46-54 of column 3) (as seen in Figures 5 and 7); a shaft (66) coupled at a distal end to the suction head (64), the shaft having a vacuum lumen (86) (as seen in Figures 2, 4 and 8); a handle (68) coupled to a proximal end of the shaft (66) (as seen in Figure 8) for remote manipulation of the position of the suction head both to and from an axially aligned position using a system of joints (62) providing for a wide range of positions including a 90 degree angle (as described in lines 37-45 of column 3); a means for locking the position of the suction head in a desired position (as described in lines 11-16 of column 4); and a means for remotely changing the position of the head (as described in lines 39-41 of column 2 and in lines 1-7 of column 3) (as seen in Figure 1). However, Snow does not teach that the suction head is compressible.

Daniel et al. teaches a heart positioning device comprising a suction head (116) in fluid communication with a vacuum passageway (108), a shaft (114, 120) with a vacuum lumen (108) (as seen in Figures 1A, 2A-B and 2C) and a handle (122); wherein the suction head is compressible from a first uncompressed condition, to a second, compressed condition upon application of a constraint or sleeve (112) (as described in lines 49-56 of column 7); wherein the suction head is adapted for slideable introduction

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through a port (as described in lines 29-36 of column 14 and lines 49-53 of column 15); wherein the handle (122) is used to manipulate the position of the suction head (as described in lines 2-7 of column 10); wherein the positioning of the suction head comprises a control wire which is either pushed or pulled (as described in lines 11-18 of column 8); wherein the proximal position of the sleeve is controlled by a retaining member or handle (110) which may be manipulated to advance or retract the sleeve with respect to the suction head, and may be used as a port extending within an incision into a chest cavity of a patient.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a suction head and restraint similar to that taught by Daniel et al. with a heart positioning device similar to that taught by Snow because a collapsible head retained by a sleeve similar to that taught by Daniel et al. is capable of performing the same functions as a head similar to that taught by Snow, and further provides ease of positioning through a minimally invasively formed penetration in a patient's chest thereby reducing trauma to the patient and minimizing the risk of entanglement with other instruments or internal body parts (as described in lines 55-59 of column 7 of Daniel et al.)

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (Patent 6936001 B1) in view of Cohen (Patent 5336252).

Snow teaches the heart positioning device of claims 1 and 8, as described above, comprising a suction head having a vacuum passageway, a shaft having a

vacuum lumen, a handle and a means for remotely changing the position of the suction head. However, Snow does not teach a spring means to change the positioning of the suction head.

Cohen teaches a surgical instrument for use in heart surgery wherein the tip deflection is controllable, the means for controlling comprising spring means (116) (as seen in Figure 15) (as described in lines 29-46 of column 13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a spring means similar to that taught by Cohen to control the deflection of a suction head similar to that in the device taught by Snow because a spring provides a mechanical force, thereby eliminating the need for that force to come from the user of the surgical equipment, thereby lessening the strain of performing surgery.

Claims 13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (Patent 6936001 B1) in view of Daniel et al. (Patent 6174307 B1) as applied to claims 12 and 19 above, and further in view of Paolitto et al. (Patent 6517563 B1).

The combination of Snow and Daniel et al. teaches a heart positioning device comprising a suction head, a shaft, a handle and a sleeve. However, this combination does not teach a suction head that includes at least three resilient legs.

Paolitto et al. teaches a suction head with at least three resilient legs (as seen in Figures 11, 12A and 12B) which are in fluid communication with the vacuum passageway (as described in lines 19-41 of column 22).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a suction head with at least three resilient legs similar to that taught by Paolitto et al. with a heart positioning device similar to that taught by the combination of Snow and Daniel et al. as a design choice because the suction head of Paolitto et al. is used in the art to perform the same functions. Furthermore, the legs on the suction head of Paolitto et al. provide greater conformity with the shape of the organ being contacted.

Claims 23 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (Patent 6936001 B1) in view of Boyd et al. (Patent 5799661).

Snow teaches a method of providing a heart positioning device comprising a flexible suction head (4) (as seen in Figure 2) having a vacuum passageway, a shaft coupled to the suction head, having a vacuum lumen (82, 84), and a handle (68) coupled to a proximal end of the shaft (as described in lines 46-54 of column 3) (as seen in Figures 5, 7 and 8); wherein the suction head is introduced into a chest cavity through an incision and the position of the suction head is remotely changed to engage the heart (as seen in Figure 15) (as described in lines 1-7 of column 3, and as described in claim 20) (as seen in Figure 1), the position of which may be secured prior to a surgical procedure and released after the procedure (as described in lines 10-16 and 31-45 of column 4); wherein securing the position of the heart positioning device is accomplished by actuating an arm attached to the heart positioning device (as seen in Figure 1); wherein it would have been obvious to one of ordinary skill in the art at the time of the invention to axially align the suction head with the shaft prior to or during

removal for ease and to avoid damaging the patient's tissue surrounding the incision.

While Snow teaches that this device can be used to perform surgical methods other than that described above (as described in lines 29-31 of column 2), including using the heart positioning device as a retractor (as described in lines 53-57 of column 4), the method step of moving the heart within the chest cavity is not taught.

Boyd et al. teaches the use of a heart positioning device comprising a suction head (192), a vacuum passageway (191), a shaft (193) and a handle (196) (as seen in Figures 33A-C, 34 and 35) for use in a method comprising introducing the suction head into a chest cavity, using the suction head has a retractor by engaging the heart with the suction head and positioning the heart into a non-physiological orientation (as described in lines 14-30 of column 18), and performing a surgical procedure (as described in lines 29-40 of column 19, and in claim 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a system and method similar to that taught by Snow to perform surgical procedures which require non-physiological positioning of the heart similar to that taught by Boyd et al. because remote manipulation of surgical equipment helps to prevent contamination of the patient at the surgical site, thereby preventing infection. Furthermore, remote manipulation of surgical equipment allows for minimally invasive procedures to be performed (as described in lines 22-29 of column 1 of Snow).

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (Patent 6936001 B1) in view of Boyd et al. (Patent 5799661) as applied to claim 23 above, and further in view of Paolitto et al. (Patent 6517563 B1).

The combination of Snow and Boyd et al. teaches a method of using a heart positioning device comprising a suction head, a shaft, a handle and a sleeve. However, this combination does not teach a suction head that includes at least three resilient legs.

Paolitto et al. teaches a method of using a suction head with at least three resilient legs (as seen in Figures 11, 12A and 12B) which are in fluid communication with the vacuum passageway (as described in lines 19-41 of column 22).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a suction head with at least three resilient legs similar to that taught by Paolitto et al. with a heart positioning device similar to that taught by the combination of Snow and Boyd et al. as a design choice because the suction head of Paolitto et al. is used in the art to perform the same functions. Furthermore, the legs on the suction head of Paolitto et al. provide greater conformity with the shape of the organ being contacted.

Claims 25-29, 34, 36-40 and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (Patent 6936001 B1) in view of Boyd et al. (Patent 5799661) as applied to claim 23 above, and further in view of Daniel et al. (Patent 6174307 B1).

Snow teaches a method of providing a heart positioning device comprising a flexible suction head (4) (as seen in Figure 2) having a vacuum passageway, a shaft

coupled to the suction head, having a vacuum lumen (82, 84), and a handle (68) coupled to a proximal end of the shaft (as described in lines 46-54 of column 3) (as seen in Figures 5, 7 and 8); wherein the suction head is introduced into a chest cavity through an incision and the position of the suction head is remotely changed to engage the heart (as seen in Figure 15) (as described in lines 1-7 of column 3, and as described in claim 20) (as seen in Figure 1), the position of which may be secured prior to a surgical procedure and released after the procedure (as described in lines 10-16 and 31-45 of column 4); wherein securing the position of the heart positioning device is accomplished by actuating an arm attached or clamped to the heart positioning device (as seen in Figure 1); wherein it would have been obvious to one of ordinary skill in the art at the time of the invention to axially align the suction head with the shaft prior to or during removal for ease and to avoid damaging the patient's tissue surrounding the incision. While Snow teaches that this device can be used to perform surgical methods other than that described above (as described in lines 29-31 of column 2), including using the heart positioning device as a retractor (as described in lines 53-57 of column 4), the method step of moving the heart within the chest cavity is not taught.

Boyd et al. teaches the use of a heart positioning device comprising a suction head (192), a vacuum passageway (191), a shaft (193) and a handle (196) (as seen in Figures 33A-C, 34 and 35) for use in a method comprising introducing the suction head into a chest cavity, using the suction head has a retractor by engaging the heart with the suction head and positioning the heart into a non-physiological orientation (as described

in lines 14-30 of column 18), and performing a surgical procedure (as described in lines 29-40 of column 19, and in claim 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a system and method similar to that taught by Snow to perform surgical procedures which require non-physiological positioning of the heart similar to that taught by Boyd et al. because remote manipulation of surgical equipment helps to prevent contamination of the patient at the surgical site, thereby preventing infection. Furthermore, remote manipulation of surgical equipment allows for minimally invasive procedures to be performed (as described in lines 22-29 of column 1 of Snow). However, this combination does not teach the use of a suction head that is compressible.

Daniel et al. teaches a heart positioning device comprising a suction head (116) in fluid communication with a vacuum passageway (108), a shaft (114, 120) with a vacuum lumen (108) (as seen in Figures 1A, 2A-B and 2C) and a handle (122); wherein the suction head is compressed from a first uncompressed condition, to a second, compressed condition upon application of a constraint (112) (as described in lines 49-56 of column 7); wherein the suction head is slideably introduction into the chest cavity of a patient through a port (as described in lines 29-36 of column 14 and lines 49-53 of column 15); wherein the handle (122) is used to manipulate the position of the suction head (as described in lines 2-7 of column 10); wherein the positioning of the suction head comprises a control wire which is either pushed or pulled (as described in lines 11-18 of column 8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a suction head and restraint similar to that taught by Daniel et al. with a heart positioning device in a method similar to that taught by the combination of Snow and Boyd et al. because a collapsible head similar to that taught by Daniel et al. is capable of performing the same functions as a head similar to that taught by the combination of Snow and Boyd et al. and further provides ease of positioning through a minimally invasively formed penetration in a patient's chest thereby reducing trauma to the patient and minimizing the risk of entanglement with other instruments or internal body parts (as described in lines 55-59 of column 7 of Daniel et al.)

Claims 35 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (Patent 6936001 B1) in view of Boyd et al. (Patent 5799661) and further in view of Daniel et al. (Patent 6174307 B1) as applied to claims 34 and 40 above, and further in view of Paolitto et al. (Patent 6517563 B1).

The combination of Snow, Boyd et al. and Daniel et al. teaches a method of using a heart positioning device comprising a suction head, a shaft, a handle and a sleeve. However, this combination does not teach a suction head that includes at least three resilient legs.

Paolitto et al. teaches a method of using a suction head with at least three resilient legs (as seen in Figures 11, 12A and 12B), which are in fluid communication with the vacuum passageway (as described in lines 19-41 of column 22).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a suction head with at least three resilient legs similar to that taught by Paolitto et al. with a heart positioning device similar to that taught by the combination of Snow and Boyd et al. as a design choice because the suction head of Paolitto et al. is used in the art to perform the same functions. Furthermore, the legs on the suction head of Paolitto et al. provide greater conformity with the irregularity of the shape of the organ being contacted.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wang et al. (Patent 5657429 and Patent 5553198) shows a system for use with surgical instruments to remotely perform surgical procedures. Cohen (Patent 5336252) shows the use of a push/pull wire and both Cohen and Snyders (Patent 5256132) show a flexible suction head compressed by a retractable sleeve (see Figures 10-11 and Figures 1-2, respectively). Foley et al. (PGPUB 2003/0078471 A1) shows a suction head with at least three resilient legs (as seen in Figures 1 and 2). In addition to the above cited recitations, Paolitto et al. (Patent 6517563 B1) shows the use of a clamp to secure a heart positioning device to an arm.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sara Lushby
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